

**REMARKS**

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-10, 12-14 and 16-20 were in the application, claims 1, 3-6, 8-9, 12-13, 16, 17 and 20 were amended, claims 2, 7, 10, 18 and 19 were cancelled, and new claims 21-27 have been added.

To avoid the use of alternative language, claim 1 has been amended to incorporate the limitations of claim 2 therein, directed to the sterilized liquid fraction and correspondingly, claim 3 has been placed in independent form, directed to the solid plant residue with new dependant claims 21, 22, 23, 25 and 27 added to depend therefrom. The term "liquid fraction" was used as opposed to the broader term "liquid" so as to distinguish the liquid separated from the plant material from other liquids, such as for example liquid nitrogen. This was done for clarity, and would be a term well understood by those skilled in the art and no new matter is involved in the use of this term.

Claims 1-10, 12-14 and 16-20 were rejected under 35 USC 112, second paragraph for various deficiencies. As to the term "intermediator", this has been further defined, consistent with the description on page 3, lines 20-25.

Claim 7 has been cancelled, rendering moot the rejection.

Claim 8 has been amended so as to separate subsections a, b and c into three separate dependant claims, claim 8 directed to subsection a, subsections b and c presented as new claims 23, 24 and 25, subsection c presented as new claim 26 which now properly depends from claim 6, not claim 1.

In claims 9 and 13, the indefinite language has been removed.

As to the terms "fast freeze" and "fast defrost", it is believed that these terms are sufficiently defined in the specification so as to be well understood by one skilled in the art.

The Federal Circuit Court has stated that the fact that "some claim language may not be precise . . . does not automatically render a claim invalid. When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree." *Seattle Box Co. v. Indus. Crating & Packaging, Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. (BNA) 568, 574 (Fed. Cir. 1984). *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1381 (Fed. Cir. 2001)

"The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1983).

As to the present claim language, a "fast freeze" is described in the specification as immersion in a cold fluid, such as liquid nitrogen, for ten seconds, with freezing to a temperature of about -130°C to -197°C (p. 3, l. 12-14). A "fast defrost" involves placing the frozen plant material in a hot fluid at a temperature of between about 80°C and 90°C, until the temperature of the material reaches about 15°C to 20°C, described on p. 3, l. 14-17. The time may vary, of course, but is stated as being about 2 minutes on page 11, six lines from the bottom. In any event, these descriptions would be more than sufficient to

give guidance to one skilled in the art as to the metes and bounds of "fast freeze" and "fast defrost". No more is needed and this part of the rejection should be withdrawn.

The rejection of claims 1, 6, 7, 9, 10 and 12 as being anticipated by Davey et al is rendered moot by the amendment to claim 1, placing in essence, claim 2 in independent form.

Similarly, the rejection of claims 1, 6, 7, 9 and 12 as being anticipated by Wu et al is rendered moot.

Claims 1-2, 4-6, 7, 9 and 12 were rejected as being obvious over Davey et al and Laugharn, Jr..

To establish a prima facie case of obviousness based on a combination of references, there should be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant. In re Raynes, 7 F.3d 1037, 1039, 28 U.S.P.Q.2D (BNA) 1630, 1631 (Fed. Cir. 1993); In re Oetiker, 977 F.2d 1443, 1445, 24 U.S.P.Q.2D (BNA) 1443, 1445 (Fed. Cir. 1992). However, the search for a teaching or suggestion should not be rigid, and a more flexible approach to a determination of obviousness should be used so as to avoid a conflict with common sense. KSR International Co. v. Teleflex Inc. et al, 2007 U.S. Lexis 4745 U.S. Supreme Court, April 30, 2007. In this decision, however, the Supreme Court reaffirmed that obviousness can not be established by a hindsight combination to produce the claimed invention. In re Gorman, 933 F.2d 982, 986, 18 U.S.P.Q.2D (BNA) 1885, 1888 (Fed. Cir. 1991). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination.

The Examiner admits that neither reference teaches the process claimed by the applicant, and points to nothing which would lead one skilled in the art to the applicants invention, and instead engages in a classic hindsight reconstruction to arrive at the applicants invention.

The examiner states that Davey et al teaches pulverizing plant tissue in liquid nitrogen for an extraction using 3% metaphosphoric acid. It is important to note that the process steps are taught for sample preparation when performing an analysis via high performance capillary zone electrophoresis, and this only being relevant to preparing the extracted liquid sample. There is nothing to teach a method for obtaining a sterilized liquid fraction, and a sterilized solid plant residue and one skilled in the art would find nothing in this reference to lead them to the applicants invention.

It is particularly difficult to combine this with Laugharn, Jr. since in the background description, it discusses how the "the traditional freeze thaw sterilization" methods were not satisfactory, and where it was also clearly stated: "Lethality is correlated with slow freezing and rapid thawing." and further:

"Traditional freeze-thaw methods are limited in the speed of the freeze-thaw cycle by the time needed to transfer heat to and from the center of the sample to effect phase changes. The equilibrium rate is particularly slow in the case of large volume samples (e.g., about 100 ml or larger). Sterilization efficiency of the traditional methods is limited by the impracticality of performing a large number of freeze-thaw cycles by those methods.

Laugharn clearly leads one away from the proposed combination, instructing that slow freezing is necessary for sterilization, and rather this patent leads one to use of a "cryobaric sterilization" process where:

"....biological and non-biological materials can be sterilized, decontaminated, or disinfected by repeatedly cycling between relatively high and low pressures. Pressure cycling can be carried out at low, ambient, or elevated temperatures (e.g., from about -40.degree. C. to about 95.degree. C.)." (Emphasis added)

Thus, one skilled in the art is lead away from the fast freeze/fast thaw sterilization discussed in the applicants' invention, and to a process where pressure, not temperature, is cycled, and this can even be undertaken at elevated temperatures which would clearly degrade the temperature sensitive components which are sought to be preserved according to the applicants' invention. Note that consistent with Laugharn, the "quick freeze" in Davey had nothing to do with sterilization. There was only one freeze done to make the sample solid so it could be pulverized and then subjected to chemical extraction. A true combination would lead one to use a slow freezing if sterilization of the sample were desired.

On the other hand, the applicants invention first subjects a plant material to a fast freeze, then the plant material is crushed, defrosted and separated into two fractions, a liquid fraction, and a solid plant residue, before each of these separated fractions are further subject to one or more fast freeze/fast thaw cold sterilization cycles. No such process is taught or suggested by the cited patents, and instead, one skilled in the art is led away from the applicants' invention.

Claims 1-6, 7, 9 and 12 were rejected as being obvious over Davey et al in view of Laugharn, Jr., as discussed above and further in view of Rooks, et al.

The discussion above relative to Davey et al and Laugharn, Jr. is equally applicable here. The addition of Rooks et al to the primary and secondary references fails to render

these claims obvious. Rooks et al describes numerous separations performed before a remainder is frozen and then once frozen, this material is pulverized so as to produce a powder for use in making various products.

Nowhere in Rooks et al is there any teaching suggestion or inference which would lead one skilled in the art to the applicants' invention, and the significant differences in the processes and products obtained in accordance with the teachings in each reference, makes it clear that the proposed combination is improper. It is quite clear that the examiner has engaged in a hindsight reconstruction, picking and choosing only those portions which allegedly support unpatentability, while disregarding what the references, as a whole, would truly teach one skilled in the art. Consequently, this combination would not lead one to the applicants invention, and the rejection should be withdrawn.

The rejection of claims 1, 6, 7-9, 10 and 12 has been rendered moot by the amendment to claim 1 as discussed above.

Claims 13-14, and 17-20 were rejected as being obvious over Davey et al, Laugharn, Jr, Rooks et al and Bracco et al.

Claim 13 has been amended to incorporate the limitations of and to depend from independent claim 3. Consequently, it is believed that this rejection has been rendered moot.

Similarly, the rejection of claims 13-14, and 16-20 over Davey et al, Laugharn, Jr. Rooks et al and Shibanaï et al has been rendered moot by the amendment.

Based on the above amendments and remarks, favorable consideration and allowance of the application are respectfully requested. However should the examiner

believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

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